K091504

10.0 510(k) Summary

Micrus Endovascular Corporation
Micrus® Ascent™ Occlusion Balloon Catheter and
Micrus® Summit™ Occlusion Balloon Catheter

JUN 19 2009

This 510(k) Summary for the Micrus® Ascent™ Occlusion Balloon Catheter and the Micrus® Summit ™ Occlusion Balloon is submitted in accordance with the requirements of 21 C.F.R. § 807.92.

GENERAL INFORMATION

Manufacturer:
Micrus Endovascular Corporation
821 Fox Lane
San Jose, CA 95131
Phone: 408-433-1400,
Est. Registration No. 2954740

Contact Person:
Patrick Lee
Phone: (408) 433-1428
Fax: (408) 433-1585
plee@micruscorp.com

Date Prepared: May 19, 2009

DEVICE CLASSIFICATION

Classification: Class II

Trade Names:
Micrus® Ascent™ Occlusion Balloon Catheter
Micrus® Summit™ Occlusion Balloon Catheter

Generic/Common Name: catheter, intravascular occluding, temporary (21CFR § 870.4450)

PREDICATE DEVICES

- 510(k) no. K080861, Micrus Ascent Occlusion Balloon Catheter, August 27, 2008

INDICATION FOR USE

The Micrus® Ascent™ and Summit™ Occlusion Balloon Catheters are intended for use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired and offers a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The Micrus Ascent and Summit Occlusion Balloon Catheters are also intended to assist in the delivery of diagnostic agents such as contrast media, and therapeutic agents such as occlusion coils, into the peripheral and neuro vasculature.

DEVICE DESCRIPTION

The Micrus Ascent and Summit Occlusion Balloon Catheters are coaxial dual lumen balloon catheters comprised of an inner guidewire lumen and a separate outer lumen to inflate and deflate the balloon. The balloon catheter is designed for use over any .014" or smaller guidewire. The balloon can be inflated and deflated independently of guidewire position. The balloon is equipped with a vent hole for easy preparation and removal of air from the balloon, and with two radiopaque markers for balloon positioning.

SUBSTANTIAL EQUIVALENCE

The Micrus Ascent and Summit Occlusion Balloon Catheters are substantially equivalent to the Micrus Ascent Occlusion Balloon Catheter (4x7mm) in terms of intended use, design, specifications, methods and materials in construction, packaging, and sterilization and materials. These systems are all intended for use to assist in the temporary occlusion of peripheral vessels, as its predicate. The modification to the device has not altered the fundamental technology of the predicate devices.

CONCLUSION

As described in this 510(k) Summary, Micrus Endovascular Corporation considers the modified Micrus Ascent Occlusion Balloon Catheters and the Micrus Summit Occlusion Balloon Catheters to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2009

Micrus Endovascular Corporation
c/o Patrick Lee
Manager of Regulatory Affairs
821 Fox Lane
San Jose, CA 95131

Re: K091504
Trade/Device Name: Micrus® Ascent™ Occlusion Balloon Catheter
Micrus® Summit™ Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: May 19, 2009
Received: May 21, 2009

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and
Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091504

Device Name: Micrus Ascent Occlusion Balloon Catheter and Micrus Summit Occlusion Balloon Catheter

Indications For Use:

The Micrus Ascent and Summit Occlusion Balloon Catheters are intended for use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired and offers a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The Micrus Ascent and Summit Occlusion Balloon Catheters are also intended to assist in the delivery of diagnostic agents such as contrast media, and therapeutic agents such as occlusion coils, into the peripheral and neuro vasculature.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K091504